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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,898	SHORROSH ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,16,20,21 and 24-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-9,16,20,21 and 24-28* is/are rejected.

7)☒ Claim(s) *10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' amendments filed November 3, 2008 were entered.

2. Claims 1, 3-10, 16, 20, 21, and new claims 24-28 are pending.

3. The objection to the specification is withdrawn in light of the amendment to Table 4 on page 28.

4. The objection to claims 14-16 is withdrawn in light of the claim cancellations and amendment.

5. The rejection of claims 1, 3-9, 14-16, 20, and 21 under 35 U.S.C. 112, first paragraph is withdrawn in light of the claim amendments.

Claim Objections

6. Claim 10 remains objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 16, 24, and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 16 is broadly drawn towards any isolated nucleic acid having at least 70% sequence identity to any fragment of the nucleotide sequence of SEQ ID NO: 1, wherein said fragment is at least 500 nucleotides in length and is capable of promoting expression in a plant cell of an operably linked nucleic acid; claims 24 and 25 limit the fragment of claim 16 to being at least 1000 or 2000 nucleotides in length, respectively.

In the response filed November 3, 2008, Applicants indicate that support for the amendment to claim 16 can be found at page 4, lines 13-20, page 5, lines 20-30, and page 8, lines 1-7 in the specification (response, page 6). However, support is not found for the amendment in the specification. The passages on pages 4 and 8 do not mention anything about percent identity or fragments. The passage on page 5 recites " In some embodiments, a novel nucleic acid of the invention has 30% or greater sequence identity to SEQ ID NO: l, for example, 35% or greater, 40% or greater, 50% or greater, 60% or greater, 70% or greater, 80% or greater, 85% or greater, 90% or greater, 95% or greater, 96% or greater, 97% or greater, 98% or greater, or 99% or greater", and "The length of a nucleic acid is, for example,'50 to 100 nucleotides, 100 to 250 nucleotides, 250 to 500 nucleotides, 500 to 1,000 nucleotides, 1,000 to 2,000 nucleotides, or

greater than 2,00 nucleotides." While support is found on page 5 for nucleic acids having a recited percent identity to SEQ ID NO: 1, and for fragment sizes, support is not found for nucleic acids having at least 70% sequence identity to any fragments of SEQ ID NO: 1. The claim amendments are NEW MATTER and must be removed.

8. Claims 1, 3-9, 16, 20, 21, and 24-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discusses the cloning and sequencing of 5' untranslated regions from the 11S globulin (SEQ ID NO: 2, not elected) and 2S albumin (SEQ ID NO: 1, elected) genes of sesame plants (pages 2-3; Figure 1). Example 2 and Table 1 indicate that several supposed regulatory elements were identified within SEQ ID NO: 1. Example 3 discusses assays showing the functionality of SEQ ID NO: 1 in transcribing an operably linked GUS sequence in transient expression assays in Brassica leaves and Example 4 discusses its functionality in transgenic Brassica plants (Tables 3 and 4). The specification concludes that the promoter of SEQ ID NO: 1 directs gene expression in Brassica seeds and embryos (page 27).

The Federal Circuit provided the appropriate standard for written description in University of California v. Eli Lilly & Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court held that a structural description of a rat cDNA was not an adequate description of broader classes of cDNAs, because a "written description of an invention involving a chemical

genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subjected matter sufficient to distinguish it from other materials.

Written description requirement can be met by "'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics.., i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *See Enzo Biochem, Inc. v. Gen-Probe Inc.,* 323 F.3d 956 (Fed. Cir. 2002).

Claim 1 is drawn towards any isolated nucleic acid having at least 70% sequence identity to SEQ ID NO: 1 and is capable of promoting expression of an operably linked heterologous nucleic acid in a plant cell. Claim 3 limits claim 1 by requiring any heterologous nucleic acid to be operably linked to the nucleic acid of claim 1. Claims 4 and 5 are drawn to transgenic plant cells or plants comprising the construct of claim 3. Claims 6 and 7 are drawn towards methods of making transgenic plant cells or plants comprising introducing the construct of claim 3 into a plant cell or plant. Claims 8, 9, 20, and 21 limit the nucleic acid of claim 1 to having at least 75%, 95%, 85%, or 98% identity, respectively, to SEQ ID NO: 1. Claim 16 is broadly drawn towards any isolated nucleic acid having at least 70% sequence identity to any fragment of the nucleotide sequence of SEQ ID NO: 1, wherein said fragment is at least 500 nucleotides in length and is capable of promoting expression in a plant cell of an operably linked nucleic acid; claims 24 and 25 limit the fragment of claim 16 to being at least 1000 or 2000 nucleotides in length, respectively. Claim 26 is drawn to any isolated nucleic acid comprising a fragment of

SEQ ID NO: 1 at least 500 nucleotides in length, wherein the nucleic acid is capable of promoting expression in a plant cell of an operably linked heterologous nucleic acid; claims 27 and 28 limit the nucleic acid of claim 26 to being at least 1000 or 2000 nucleotides in length, respectively.

However, the only isolated nucleic acid described by the specification is SEQ ID NO: 1 itself. SEQ ID NO: 1 consists of 2400 nucleotides. Claim 1 encompasses nucleic acids that differ from SEQ ID NO: 1 by as much as 30%, or 720 nucleotides. It is noted that Example 2 and Table 1 supposedly identify numerous regulatory elements in SEQ ID NO: 1. However, it is noted that many of these elements are described as required for activities which the specification does not mention is possessed by SEQ ID NO: 1. For example, sequences are noted for ABA-responsiveness; light regulation; an AP2-like binding consensus for Arabidopsis transcription factor RAV1; a motif in a soybean 7S globulin gene; gibberellin responsiveness; cis-elements found in phenylalanine ammonia lyase genes; elements for ethylene responsiveness. Yet the specification does not describe SEQ ID NO: 1 as responding to light, ABA, gibberellin, or ethylene, for example. An element, CA(n), is listed, which confers endosperm specificity, and which the working examples do not show for SEQ ID NO: 1. A sequence is noted only for being present in an oleosin promoter. One domain is even described as "Unknown". The importance of these domains to the functional activity of SEQ ID NO: 1 is unknown. Several domains are noted as conferring seed or embryo specificity. However, they are scattered throughout the 2400 base sequence of SEQ ID NO: 1. The specification does not actually describe that any of these sequences actually are required for transcriptional activity, or which ones confer seed and embryo specificity to SEQ ID NO: 1.

Further, it is noted that the domains listed in Table 1 are found throughout SEQ ID NO: 1. If all of these domains are required for activity, then fragments as small as 500 nucleotides, and nucleic acids that further differ from those fragments by as much as 30%, will not possess the transcription promoting activity of SEQ ID NO: 1. Not a single nucleic acid encompassed by claim 16 is disclosed in the specification and correlated with activity of SEQ ID NO: 1. Given the breadth of the claims and the description in the specification of only single nucleic acid encompassed by the claims, SEQ ID NO: 1, it is submitted that the specification fails to provide an adequate written description of the multitude of isolated nucleic acids encompassed by the claims.

9. Claims 1, 3-9, 16, 20, 21, and 24-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1, does not reasonably provide enablement for isolated nucleic acids that differ from SEQ ID NO: 1 and have its activity of promoting expression of an operably linked heterologous nucleic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

As noted above, the specification discusses the cloning and sequencing of the 5' untranslated region (SEQ ID NO: 1) of the 2S albumin gene of sesame plant. Example 2 and Table 1 indicate that several supposed regulatory elements were identified within SEQ ID NO: 1. Example 3 discusses assays showing the functionality of SEQ ID NO: 1 in transcribing an operably linked GUS sequence in transient expression assays in Brassica leaves and Example 4 discusses its functionality in transgenic Brassica plants (Tables 3 and 4). The specification

concludes that the promoter of SEQ ID NO: 1 directs gene expression in Brassica seeds and embryos (page 27).

However, the specification does not teach isolated nucleic acids that differ from the 2400 base sequence of SEQ ID NO: 1 by as much as 30%, while retaining its activity of directing transcription in plant seeds and embryos. It is noted that the specification in Example 2 identifies putative regulatory regions. However, the importance of these regions to the activity of SEQ ID NO: 1 was not confirmed experimentally. Many of these elements are described as required for activities which the specification does not mention is possessed by SEQ ID NO: 1. For example, sequences are noted for ABA-responsiveness; light regulation; an AP2-like binding consensus for Arabidopsis transcription factor RAV1; a motif in a soybean 7S globulin gene; gibberellin responsiveness; cis-elements found in phenylalanine ammonia lyase genes; elements for ethylene responsiveness. Yet the specification does not describe SEQ ID NO: 1 as responding to light, ABA, gibberellin, or ethylene, for example. An element, CA(n), is listed, which confers endosperm specificity, and which the working examples do not show for SEQ ID NO: 1. A sequence is noted only for being present in an oleosin promoter. One domain is even described as "Unknown". The importance of these domains to the functional activity of SEQ ID NO: 1 is unknown. Several domains are noted as conferring seed or embryo specificity. However, they are scattered throughout the 2400 base sequence of SEQ ID NO: 1, and there is no indication as to whether they actually do confer seed and/or embryo specificity to the SEQ ID NO: 1. In the absence of further guidance, undue experimentation would be required by one skilled in the art to determine which, if any, of the supposed regulatory regions mentioned in Table 1 are actually required for the transcriptional activity of SEQ ID NO: 1. Undue

experimentation would also be required to determine the 30% of the sequences of SEQ ID NO: 1 that can be altered, and what to change them to, without affecting its transcriptional activity.

Claim 16 encompasses isolated nucleic acids having at least 70% sequence identity to any fragment of SEQ ID NO: 1 that is at least 500 nucleotides in length. If all of these domains are required for activity, then fragments as small as 500 nucleotides, and nucleic acids that further differ from those fragments by as much as 30%, would not retain the transcription promoting activity of SEQ ID NO: 1. The specification does not provide a single example of a nucleic acid encompassed by claim 16 that retains the activity of SEQ ID NO: 1. See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Given the breadth of the claims, lack of guidance in the specification and unpredictability of the art, undue experimentation would be required by one skilled in the art to make and use the invention as claimed.

Summary

10. Claim 10 is objected and claims 1, 3-9, 16, 20, 21, and 24-28 are rejected.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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January 29, 2009

/Ashwin Mehta/
Primary Examiner, Art Unit 1638